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FORM

10-07-02

March 1, 2002

Kesavan ESUVARANATHAN

Date of Deposit: October 3, 2002

PTO/SB/21708-00)

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First Named Inventor

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Group Art Unit

(to be used for all corresponde	Examiner Name	To Be Assigned	d			
Total Number Of Pages In This Subm	Attorney Docket No.	488002000200				
ENCLOSURES (check all that apply)						
Fee Transmittal Form		signment Papers r an Application)		After Allowance Communication to Group		
Fee Attached	Dra	awing(s)		Appeal Communication to Board of Appeals and Interferences		
Amendment / Reply	Lic	ensing-related Papers		Appeal Communication to Group (Appeal Notice, Brief, Reply Brief)		
After Final	Pe	lition		Proprietary Information		
Affidavits/declaration		tition to Convert to a ovisional Application		Status Letter		
Extension of Time Request		wer of Attorney, Revocation ange of Correspondence Add	dress 🗶	Other Enclosure(s) (please identify below):		
Express Abandonment Req	uest 🗀	minal Disclaimer quest for Refund		Form PTO-1449 + 2 copies (21 Pages) 108 References Return Receipt Postcard		
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Certified Copy of Priority Do	cument(s) Remarks					
Response to Missing Parts/ Incomplete Application		_				
Response to Missing under 37 CFR 1.52 c						
SIGNATURE OF APPLICANT, ATTORNEY OR AGENT						
Firm Morriso		Mill Road, Palo Alto, California 9		IV I		
or						
Individual Name Madelin	e I. Johnston (Registration I	No. 36,174)				
Signature	1000/					
Date October	3, 2002					
CERTIFICATE OF MAILING BY "EXPRESS MAIL"						

Tamara Alcaraz Burden Hours Statement: This form is estimated to take 0.2 hours to complete. The will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Officer Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Box Patent Application, Washington, DC 20231.

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Docket No. 4880020002

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mara Alcaraz

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

#3/ I.D.S.

In the application of:

Kesavan ESUVARANATHAN, et al.

Serial No.:

10/086,973

Filing Date:

March 1, 2002

For:

METHODS AND COMPOSITIONS FOR

DELIVERY OF PHARMACEUTICAL

AGENTS

INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. § 1.97 AND § 1.98

Assistant Commissioner for Patents Washington, D.C. 20231

Dear Sir:

Pursuant to 37 C.F.R. § 1.97 and § 1.98, Applicants submit for consideration in the above-identified application the documents listed on the attached Form PTO-1449. Copies of the documents are also submitted herewith. The Examiner is requested to make these documents of record.



This Information Disclosure Statement is submitted:

Ш	With t	the application; accordingly, no fee or separate requirements are required.
\boxtimes	Within	n three months of the application filing date or before mailing of a first Office
	Action	on the merits; accordingly, no fee or separate requirements are required.
	After	receipt of a first Office Action on the merits but before mailing of a final Office
	Action	or Notice of Allowance.
		A fee is required. A check in the amount of is enclosed.
		A fee is required. Accordingly, a Fee Transmittal form (PTO/SB/17) is attached
		to this submission in duplicate.
		A Certification under 37 C.F.R. § 1.97(e) is provided below; accordingly; no fee
		is believed to be due.
	After 1	mailing of a final Office Action or Notice of Allowance, but before payment of the
	issue f	èee.
		A Certification under 37 C.F.R. § 1.97(e) is provided below and a check in the
		amount of is enclosed.
		A Certification under 37 C.F.R. § 1.97(e) is provided below and a Fee Transmittal
		form (PTO/SB/17 is attached to this submission in duplicate.

Applicants would appreciate the Examiner initialing and returning the Form PTO-1449, indicating that the information has been considered and made of record herein.

The information contained in this Information Disclosure Statement under 37 C.F.R. § 1.97 and § 1.98 is not to be construed as a representation that: (i) a complete search has been made; (ii) additional information material to the examination of this application does not exist; (iii) the information, protocols, results and the like reported by third parties are accurate or enabling; or (iv) the above information constitutes prior art to the subject invention.



In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, Applicants petition for any required relief including extensions of time and authorize the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing <u>488002000200</u>. However, the Assistant Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Dated: October 3, 2002

Respectfully submitted,

By:

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#3/I.D.S.

PTO/SB/08 (2-92)

Form PTO-1449

INFORMATION DISCLOSURE CITATION IN AN APPLICATION

(Use several sheets if necessary)

Ocket Number 488002000200

Application Number 10/086,973

Applicant

Kesavan ESUVARANATHAN, et al.

Filing Date March 1, 2002

Group Art Unit 1645

Mailing Date: October 3, 2002

U.S. PATENT DOCUMENTS

Examiner Initials	Ref. No.	Date	Document No.	Name	Class	Subclass	Filing Date If Appropriate
	1.	11/23/1993	5,264,618	Felgner et al.			

FOREIGN PATENT DOCUMENTS

Examiner Initials	Ref. No.	Date	Document No.	Country	Class	Subclass	Translation YES NO
	2.	10/27/1994	CA 2,161,225	Canada			
	3.	12/28/1995	CA 2,193,502	Canada			
	4.	03/21/1996	CA 2,199,004	Canada			
	5.	02/26/1998	CA 2,263,705	Canada			
	6.	04/01/1999	CA 2,303,884	Canada			
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	8.	03/21/1996	WO 96/08235 A1	WIPO			
	9.	11/28/1996	WO 96/37194 A1	WIPO			
	10.	12/19/1996	WO 96/40962 A1	WIPO			
	11.	12/19/1996	WO 96/40963 A1	WIPO			
	12.	02/26/1998	WO 98/07408 A1	WIPO			
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	16.	11/19/1998	WO 98/51285 A2	WIPO			
	17.	04/01/1999	WO 99/15206 A1	WIPO			

OTHER DOCUMENTS

(including author, title, Date, Pertinent Pages, Etc.)

Examiner Initials	Ref. No.	Title
	18.	A Conference Supplement to Cancer Gene Therapy. (November/December 1999) Gene Therapy of Cancer VIII. San Diego, California December 9-11, 1999. 6(6):total pages 2.

EXAMINER:

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PTO/SB/08 (2-92) Sheet 2 of 7

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Form PTO-	Form PTO-1449		Docket Number 488002000200	Application Number 10/086,973		
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Sheet 5 of 7

TECH CENTER 1600/2000cket Number 488002000200 Form PTO-1449 Application Number 10/086,973 INFORMATION DISCLOSURE CITATION Applicant IN AN APPLICATION Kesavan ESUVARANATHAN, et al. (Use several sheets if necessary) Filing Date March 1, 2002 Group Art Unit 1645 OCT 0 3 2002 Mailing Date: October 3, 2002 Morales, A. et al. (August 1976). "Intracavitary Bacillus Calmette-Guerin in the Treatment of TRADEMA? Superficial Bladder Tumors," J. Urol. 116:180-183. Morris, B. D. et al. (August 1994). "Adenoviral-mediated Gene Transfer to Bladder In Vivo," J. 70. Urol. 152:506-509. Nabel, G. J. et al. (December 1993). "Direct Gene Transfer with DNA-liposome Complexes in 71. Melanoma: Expression, Biologic Activity, and Lack of Toxicity in Humans," Proc. Natl. Acad. Sci. USA 90:11307-11311. Nabel, E. G. et al. (September 1990). "Site-specific Gene Expression In Vivo by Direct Gene Transfer 72. int o the Arterial Wall," Science 249(4974):1285-1288. Nabel, E. G. et al. (June 1992). "Transduction of a Foreign Histocompatibility Gene into the Arterial 73. Wall Induces Vasculitis," Proc. Nat. Acad. Sci. USA 89(11):5157-5161. Nseyo, U. O. and Lamm, D. L. (October 1996). "Therapy of Superficial Bladder Cancer," Semi. in 74. Oncol. 23(5):598-604. Otsuji, M. et al. (November 1996). "Oxidative Stress by Tumor-deprived Macrophages Suppresses 75. the Expression of CD3 & Chain of T-Cell Receptor Complex and Antigen-specific T-Cell Responses," Proc. Natl. Acad. Sci. USA 93:13119-13124. Pang, L. et al. (1999). "Membrane Cholesterol Modulates Galanin-GalR2 Interaction," Biochem. 76. 38(37):12003-12011. 77. Patard, J. J. et al. (1998). "Immune Response Follwing Intravesical Bacillus Calmette-Guerin Instillations in Superficial Bladder Cancer: A Review," Urol. Res. 26:155-159. 78. Plautz, G. E. et al. (May 1993). "Immunotherapy of Malignancy by In Vivo Gene Transfer into Tumors," Proc. Nat. Acad. Sci. USA 90:4645-4649. 79. Rajewski, R. A. and Stella, V. J. (November 1996). "Pharmaceutical Applications of Cyclodexrins. 2. In Vivo Drug Delivery," J. Pharm. Sci. 85(11):1142-1169. Rodal, S. K. et al. (April 1999). "Extraction of Cholesterol with Methyl-β-Cyclodextrin Perturbs 80. Formation of Clathrin-coated Endocytic Vesicles," Mol. Biol. Cell 10:961-974. Ruponen, M. et al. (1999). "Interactions of Polymeric and Liposomal Gene Delivery Systems with 81. Extracellular Glycosaminglycans: Physicochemical and Transfection Studies," Biochem. et Biophys. Acta 1415:331-341. 82. Saito, S. et al. (July 1994). "Immunotherapy of Bladder Cancer with Cytokine Gene-modified Tumor Vaccines," Can. Res. 54:3516-3520. 83. Salazar-Onfray, F. (1997). "Down-Regulation of the Expression and Function of the Transporter Associated with Antigen Processing in Murine Tumor Cell Lines Expressing IL-10," J.Immun. 159:3195-3202. Sander, B. et al. (August 1996). "Localization of IL-1, IL-2, IL-4, IL-8 and TNF in Superficial 84. Bladder Tumors Treated with Intravesical Bacillus Calmette-Guerin," J. Urol. 156:536-541. **EXAMINER:** DATE CONSIDERED: EXAMINER: Initial if citation considered, whether or not the citation conforms with MPEP 609. Draw a line through the citation if not in conformance and not considered. Include a copy of this form with next communication to applicant.

Form PTO-1	1449		Docket Number 488002000200	Application Number 10/086,973		
INFORM	INFORMATION DISCLOSURE CITATION		Applicant			
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			Mailing Date: October 3, 2002		
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